

7. A method according to claim 6, wherein the formulation is applied to the vagina or the clitoris.
8. A method according to claim 7, wherein the misoprostol or a metabolite of misoprostol is selected from the group consisting of a racemic mixture, an enantiomer in a (+) or (-)R form and an enantiomer in a (+) or (-)S form.
9. A method according to claim 6, wherein the formulation includes a galenic preparation.
10. A method according to claim 6, wherein the formulation is selected from the group consisting of a gel, an aqueous solution, an ointment, vaginal ovules and a system of controlled transdermal absorption.
11. A method according to claim 6, further comprising a vasodilatory agent additional to the at least one of misoprostol and its metabolite for providing an enhanced beneficial treatment of sexual dysfunction in the subject.
12. A method according to claim 11, wherein the additional vasodilatory drug is alprostadil.
13. A method according to claim 6, further comprising a passage accelerator for increasing absorption of at least one of misoprostol and a metabolite of misoprostol and optionally an additional vasodilator.
14. A method according to claim 6, further comprising an agent for treating sexual dysfunction that minimizes adverse effects arising from an otherwise toxic amount of the misoprostol or the metabolite of misoprostol and enhances the beneficial treatment of sexual dysfunction.

BEST AVAILABLE COPY

15. A method according to claim 14, wherein the agent is a-cyclodextrin.
16. A method according to claim 15, wherein the beneficial effect is vasodilation leading to sexual desire.
17. A method according to claim 6, wherein the formulation comprises a gel.
18. A method according to claim 17, wherein the gel is a low viscosity gel.
19. A method according to claim 6, wherein the formulation comprises a vanishing cream formulation.
20. A method according to claim 6, wherein the formulation comprises gelatin.
21. A method for treating sexual dysfunction in a female subject, comprising
- (a) providing a mixture including misoprostol or misoprostol metabolite, hydroxypropyl methylcellulose and water; and
  - (b) administering the mixture to a female subject.
22. A method according to claim 21, wherein the effective dose of misoprostol or misoprostol metabolite is in the range of 0.3-0.9% w/v, and the formulation further includes hydroxypropyl methyl cellulose comprising hydroxypropyl methyl cellulose 3000 at about 4% w/v.
23. A pharmaceutical composition, comprising an effective dose of at least one of misoprostol or misoprostol metabolite for treating sexual dysfunction in women.
24. A pharmaceutical composition according to claim 23, further comprising a methylcellulose.

BEST AVAILABLE COPY

25. A pharmaceutical composition according to claim 24, wherein the methylcellulose is selected from carboxymethylcellulose and hydroxypropyl methyl cellulose.

26. A pharmaceutical composition according to claim 18, further comprising a mixture of more than one vasodilatory agent.

In the specification

Please delete the title "Use of Misoprostol or/and Misoprostol acid for Preparing Drug in order to cure Sexual Dysfunction in Women." and add --Use of Misoprostol and/or Metabolites of Misoprostol for Treating Sexual Dysfunction in Women--

Conclusion

In view of the foregoing amendments, applicant submits that the claims are now in condition for allowance. Early and favorable reconsideration of the application is therefore respectfully solicited.

It is believed that no extension of time is required, however, in the event that an extension is required, applicants hereby petition same and request that any extension or other fee required for the timely consideration of this application be charged to Deposit Account No. 19-4972.

Respectfully submitted,



Harriet M. Strimpel, D.Phil  
Registration No. 37,008  
Attorney for Applicants  
Bromberg & Sunstein, LLP  
125 Summer Street  
Boston, MA 02110  
(617) 443-9292

Date: February 9, 2001  
144573

BEST AVAILABLE COPY